



February 2025

Changing the Treatment
Paradigm for Patients with Iron
Deficiency Anemia



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## **Shield Therapeutics**

Fast Growing, Mission Driven, Specialty Pharmaceutical Company

ACCRUFeR®/FeRACCRU® (ferric maltol), is the only FDA approved oral iron broadly indicated for use in adults suffering from iron deficiency, with or without anemia. Also approved by EMA and Health Canada.

Vast market opportunity in iron deficiency replacement therapy market. Traditional oral irons often lead to discontinuation due to intolerable GI side effects or insufficient efficacy<sup>1</sup>

Experienced Executive Team with extensive US commercialization expertise

Viatris co-commercialisation agreement has catalysed commercial expansion, resources and growth for ACCRUFeR®

Peak revenue potential of ACCRUFeR® of ~\$450M2

Strong IP through 2035



# Management team







**Santosh Shanbhag** CFO



**Lucy Huntington-Bailey** General Counsel



**Andy Hurley** Chief Commercial Officer



**David Childs** VP, Manufacturing and Strategic Alliance



Dr. Jackie Mitchell VP, Quality, Clinical and Regulatory Affairs



































# Iron Deficiency without & with Anemia (ID/IDA)

A highly prevalent and serious condition

Significant impact on quality of life

Symptoms include extreme fatigue, headache, vertigo, numbness in extremities, cognitive impairment

Prevalence is highest in women of childbearing age and patients with inflammatory conditions.<sup>1</sup>

Caused by malnutrition, malabsorption, or bleeding

# The New York Times

#### **IRON DEFICIENCY NEWS**

Oct 23 -- More Than a Third of Women Under 50 Are Iron-Deficient,



### Women's Health

- Menorrhagia
- Pregnancy
- Uterine Fibroids



### Inflammatory bowel disease

- · Crohn's disease
- Ulcerative colitis



Chronic kidney disease



# Universal problem: HCP's are struggling to treat IDA because patients can't tolerate the GI side effects of oral iron salts

Oral ferrous salts dissociate in the stomach. Unabsorbed iron (Fe+) generates reactive oxidative species (ROS), causing irritation and damage to the intestinal lining and gastrointestinal (GI) side effects

Up to 70% of patients can experience GI related side effects<sup>1,2</sup> including bloating, dark stool, nausea distention

Patients comment: "Side effects of oral iron worse than the symptoms of IDA"

**Up to 60%** of patients will discontinue treatment with ferrous (iron) salts primarily due to GI adverse events and lack of effectiveness<sup>3</sup>

<sup>2.</sup> Tolkien Z, Stecher L, Mander AP, Pereira DIA, Powell JJ. Ferrous sulfate supplementation causes significant gastrointestinal side-e ects in adults: a systematic review and meta-analysis. PLoS One



<sup>1.</sup> DeLoughery TG. Safety of oral and intravenous iron. Acta Haematol. 2019;142(1):8-12. doi:10.1159/000496966

# ACCRUFeR® designed for efficacy and tolerability

Unique MOA (mechanism of action) Shields and Delivers Elemental Iron to the Small Intestine 1,2

### **Proprietary formulation**

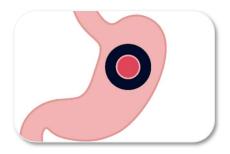
ACCRUFER® is formulated in a maltol complex vs. traditional oral irons, provided in ferrous-based formulations

#### Low iron dose

60 mg of elemental iron is delivered by ACCRUFeR® daily

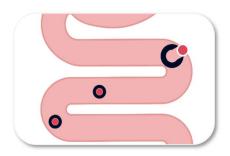
- . ACCRUFER™ is dosed at 30mg BID, MOA = mechanism of action
- 2. ACCRUFeR® (ferric maltol) [Prescribing Information]. Austin, TX: Shield Therapeutics, 2019. Revised 02/22.
- 3. Shield graphic for illustrative purposes only

# ACCRUFeR® remains tightly bound in the stomach



The maltol shield protects iron from the stomach, remaining tightly bound as it passes through

# Dissociates upon uptake in the duodenum

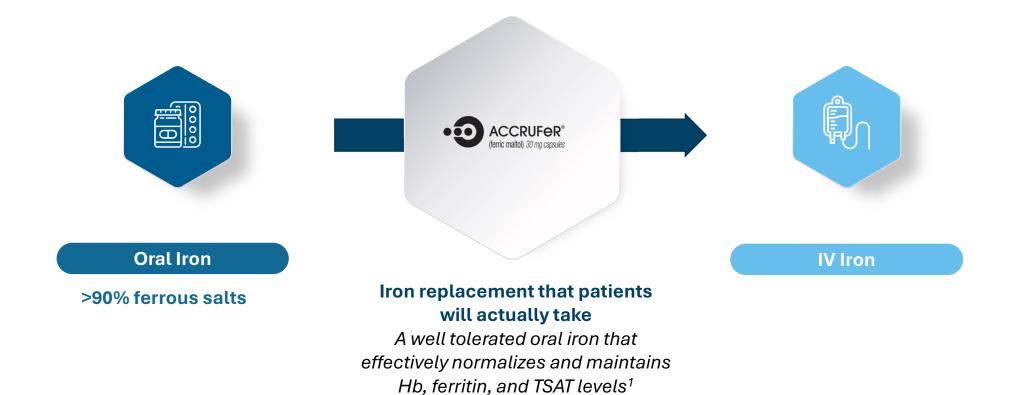


Iron remains bioavailable, chelated, and ready to replenish iron stores.

Excess iron is excreted in the stool



# Significant window of opportunity exists for ACCRUFeR®





## Global partnerships continue to progress

Deals include upfronts, milestones & double-digit royalties



#### **United States**

Co-Commercial
Agreement, Dec. 2022
Sales team in place

\$30m in available sales milestones



#### EU+1

Currently commercialized across Europe

Royalties and milestone payment upon approval for Pediatrics in EU



#### Canada

Approved by Health
Canada in August 2024
Launch expected in early
2025

Revenue-based milestone payments and Double-digit royalties on net sales



#### Republic of Korea

Filed for approval; Pending successful review, approval anticipated in 2025

Mid-teens royalties on net sales



#### China +2

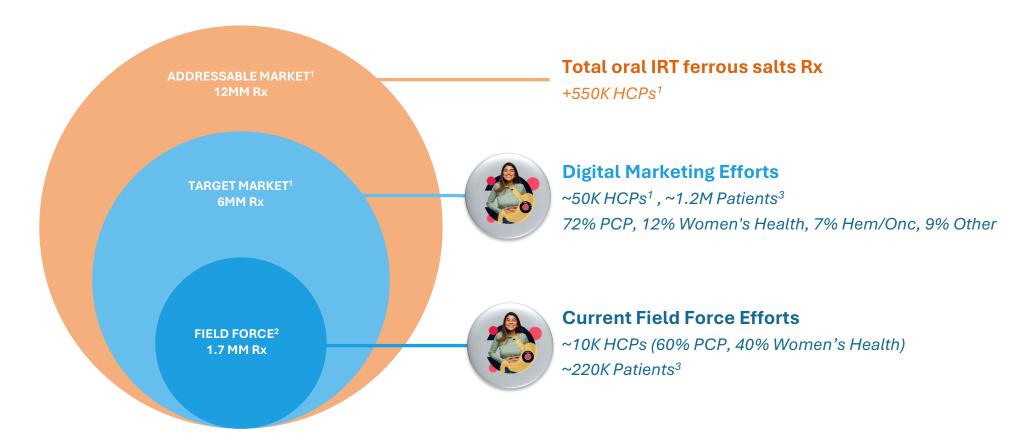
Phase 3 Study fully recruited Approval expected in H2 2026

Approval Milestone
Double-digit royalties
on net sales

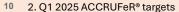
Shield will continue to evaluate further partnerships in selected geographies



# The US ID/IDA market is ideal for big upside potential for ACCRUFeR®



1. 2023 IQVIA Xponent PlanTrak + consignment (ACCRUFeR®, ferrous sulfate, integra, ferralet, proferrin, ironspan, slow Fe+, iron combo product, and other ferrous elemental irons)



3. Patients taking Oral Iron Salts and have GI Side Effects estimated to be ~45%-50% based on HCP and patient quant 2024

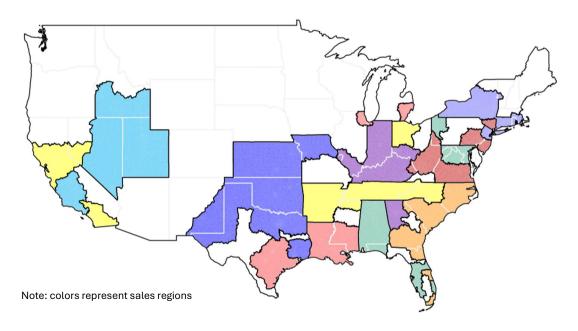


# Realignment of US sales team focusing on territories with highest potential, optimal coverage and strong ACCRUFeR® performance

#### Top 5 states ~60% of volume

- TX 17% with 6.7M covered lives (unrestricted)
- NY 17% with 6M covered lives and 70% of Rx not requiring a PA
- CA 9% with 7.9M covered lives and 99% PA approval with MediCal
- FL 9% with 4.4M covered lives (unrestricted)
- GA 7% with 3.3M covered lives (unrestricted)

#### **Optimized Footprint**

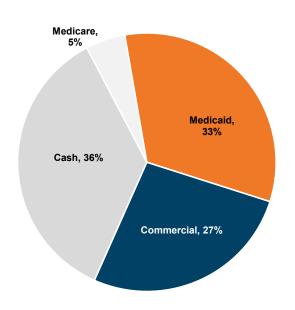




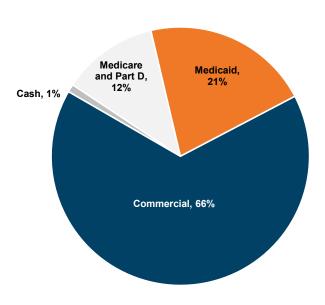
### ACCRUFeR® covered across ~70% of lives in the US

~55% of total 173M Commercial Insurance lives; ~97% of total 35M Managed Medicaid lives; 100% of total 40M Medicaid FFS (Fee for Service) lives

2024 Channel Mix - Oral Iron Salts1



2024 Channel Mix - ACCRUFeR®





# Key ACCRUFeR® initiatives to drive growth and profitability





#### **Decrease impact of consignment business**

Modified pricing program to decrease the number of loss-making prescriptions



#### Realignment of sales force to territories with

- Highest potential
- Optimal coverage
- Strong ACCRUFeR® performance



#### Increase awareness of ACCRUFeR®

Patients and HCPs via digital marketing/initiatives



# Q4 2024 and FY 2024 business update - Unaudited

Growth in
ACCRUFeR°
Revenues, TRx &
Gross to Net

Increased balance sheet and operational flexibility

Expand global patient access of ferric maltol

\$32.2M FY24 Total Revenues

#### **ACCRUFeR®**

\$29.3M FY24 Net Revenues, 153% over FY23 \$11.2M Q4, 56% growth over Q3 \$237 Q4 Net Price/Rx v. \$167 in Q3 c.41K Q4 TRx, 22% consignment<sup>1</sup> v. 37% in Q3 ~\$31M in financings in 2024<sup>2</sup>

\$6.5M YE cash + \$10m AOP<sup>3</sup> funding received on Jan 3, 2025

Reset OpEx base to be cash flow positive by end of 2025

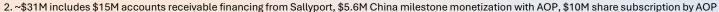
China, Ph 3 recruited

Health Canada approval

Pediatric pivotal trial successful

S. Korea, approval submission

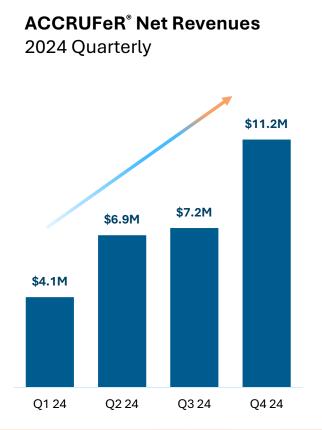
<sup>1.</sup> Consignment business represents prescriptions that were dispensed at no cost or at a significantly subsidized price to patients and were not reimbursed by payors



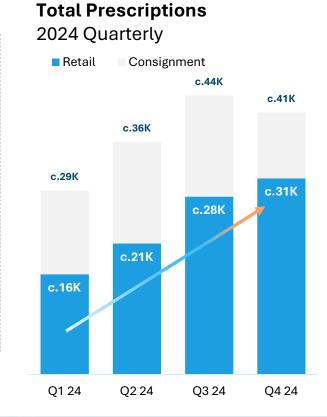
3. AOP = AOP Health International Management AG



# Strong growth in ACCRUFeR® in the US in Q4 2024









## **2025 Business Priorities**





## **Shield Therapeutics**

Fast Growing, Mission Driven, Specialty Pharmaceutical Company



- Vast market opportunity with significant revenue potential
- ACCRUFeR®/FeRACCRU® (ferric maltol) approved by the FDA, EMA, and Health Canada
- Shield-Viatris partnership driving growth in ACCRUFeR® prescriptions, net revenue and net selling price in the US
- Global partnerships continue to progress at a steady pace with anticipated milestones and double-digit royalties
- Increased balance sheet and operational flexibility
- Goal to be cash flow positive by end of 2025





# **Thank You!**

Anders Lundstrom - Chief Executive Officer Santosh Shanbhag - Chief Financial Officer

www.shieldtherapeutics.com

